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**REMARKS**

This Amendment is being submitted in response to the Office Action of June 2, 2004. Upon entry of this Amendment, claims 1, 2, 3-15 remain in the application.

This action is being submitted under the provisions of 37 C.F.R. 1.116. It is submitted that by this action, the applicant seeks to present claims in a manner suitable for allowance. Alternately, the applicant seeks to present claims in a manner that reduces the issues for consideration on appeal. Entry of this amendment is respectfully requested.

The Office Action of June 2, 2004 has been received and carefully considered. In response thereto, this Amendment is submitted. It is submitted that, by this Amendment, all bases of rejection and objection are traversed and overcome. Reconsideration is, therefore, respectfully requested.

Claim 15 has been objected to because of informalities. Claim 15 has been amended paying careful attention to the suggestions made by the Examiner.

Claims 1, 2, and 6-15 currently stand rejected under 35 U.S.C. 102(e) as being unpatentable over U.S. Patent No. 6,126,597 to Smith et al. The Examiner contends that the Smith reference teaches an item having an absorbent element (undergarment 12) capable of absorbing and retaining bodily fluid and having an analysis device 34 capable of measuring a composition of the body fluid. The analysis device 34 is considered to be disposed at an area of the hygiene item on which the bodily fluid can impinge and is separated from the absorbent element (undergarment 12) by separating means (upper outer layer 26 and lower outer layer 28). The Examiner indicates that separating means 28 may be a polyethylene film.

The applicants' invention as set forth in claim 1 is a single-use hygiene item that comprises a disposable absorbent element configured to absorb and retain bodily fluid passed by the user. Support for disposability of the absorbent element is found in Paragraph 23. The single-use hygiene item also comprises an analysis device that includes means for analyzing at least one characteristic of bodily fluid passed by the user, means for facilitating direct impingement of a portion of the bodily fluid passed by the user into contact with the analysis means separate from contact with the absorbent element, and means for disposing the analysis device on the absorbent element. The disposable, single-use hygiene item also includes means for separating the bodily fluid in the analysis device to be analyzed from the absorbent element

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in an essentially fluid tight manner. The separating means is configured to retain bodily fluid that has penetrated to the absorbent element away from the analysis device and to prevent bodily fluid contaminated by the absorbent material from falsifying analysis of the analysis device.

It is respectfully submitted that the Smith reference lacks teaching of a single-use hygiene device having an absorbent element and an analysis device directed to a pad 10 used with an undergarment or panty 12. The undergarment 12 is not configured to absorb and retain bodily fluid passed by the user. The Smith reference clearly states that where absorbency is desired to allow the article 10 to double as an absorbent pad, a suitable absorbent hydrophilic fiber intended to absorb and contain liquid may be used. (See Smith, column 5, lines 20-25.) Further in the reference, the Smith teaches that the article 10 can be configured to function simultaneously as a feminine napkin or pad or panty liner or shield. (See column 6, lines 39-41.) Thus, it can be seen that the undergarment or panty 12 disclosed in the Smith reference does not teach or suggest a single-use hygiene item having an absorbent element and an analysis device configured to accept direct impingement of bodily fluids separate from fluid absorbed and retained in the absorbent element..

Attention is also directed to column 5, lines 8-10 of the Smith reference that states that the upper layer 26 and the lower outer layer 28 provide a mere carrier for the pH-sensitive component 34. This being the case, it is submitted that the Smith reference lacks teaching of the distinct element of the present invention and that the combination of panty 12 and article 10 cannot constitute a single-use hygiene item having an absorbent element. Assuming arguendo that the teaching of column 5, lines 10-19 disclose the use of a sanitary napkin, it should noted that the Smith reference states:

However, the lower outer layer 28 would be entirely or partially composed of an absorbent material or an additional absorbent layer (not shown) would be added between the upper outer layer 26 and the lower outer layer 28 with a pH-sensitive component . . . (Smith, Column 5, lines 14-18).

It is submitted that article 10 taught in the Smith reference is, at most, a device like a sanitary napkin or panty liner. In such instances the lower outer layer 28 is configured

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to be absorbent and not a fluid-type barrier, or a further absorbent layer would be interposed between the upper layer 26 and outer layer 28. In either situation, the Smith references lack any teaching or suggestion that a separating means isolating this further absorbent layer from the analyzing means 34.

In contrast, the Applicants' invention includes a single-use hygiene item having a disposable absorbent element configured to absorb and retain bodily fluid. The item also includes an analysis device including means for analyzing a characteristic of the body fluid passed by the user, means for facilitating direct impingement of a portion of the bodily fluid passed by the user into contact with the analysis means separate from contact with the absorbent element, as well as means for disposing the analysis on the absorbent element. It is respectfully submitted that the Smith reference lacks any teaching directed to the means for disposing the analysis device on an absorbent element. In contrast, the analysis device disclosed in Smith is one that is placed on an garment item such as a panty or the like. Furthermore, the device of the present invention includes means for separating the bodily fluid collected in the analysis device to be analyzed from the absorbent element. It is further submitted that the Smith reference lacks any teaching that would teach or suggest this separation of bodily fluid portions. It is respectfully submitted that the Smith reference lacks any teaching that would direct the skilled artisan to an analysis device having bodily fluid impinged thereon while being isolated from an absorbent device. For these reasons, it is submitted that the Applicants' invention as set forth in claim 1 is not taught, anticipated, or rendered obvious by the cited reference.

Claim 2 also stands rejected under 35 U.S.C. § 102(e) as being unpatentable over U.S. Patent No. 6,126,597 to Smith et al. Claim 2 depends from claim 1 to specify that the separating means is configured as an insert in the absorbent element and contains the analysis device. It is respectfully submitted that the Smith reference lacks any disclosure that would suggest or teach separating means configured as an insert in the absorbent element to contain an analysis device. Thus, it is submitted that the Applicants' invention as set forth in claim 2 is not taught, anticipated, or rendered obvious by the cited reference.

The Examiner contends with regard to claim 2 that the separating means disclosed in Smith forms an insert 10 containing the analysis device in the absorbent element

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12 therein. The Examiner indicates that an "insert" is to be understood as an area of the hygiene item separated by the separating means from the remainder of the absorbent element and refers to paragraph 12 on page 4 of the present specification. It should also be noted that the specification indicates that the insert 2 is integrated into a standard hygiene item with an analysis device located in it (see paragraph 18, at page 5). Finally, it should be noted that the Smith reference clearly states that it is a further object of the present invention to provide an article that is worn like a sanitary napkin or pad and which may also provide the function of such sanitary items. Given the clear intention of the Smith reference, it is difficult to construe that the device 10 is an "insert" within the undergarment 12 as defined in the present invention.

Additionally, claim 2 depends from independent claim 1 to contain all of the limitations found therein. By this dependency, it is submitted that the Applicants' invention as set forth in claim 2 is not taught, anticipated, or rendered obvious by the Smith reference for the reasons discussed previously in conjunction with claim 1.

Claims 6-14 also stand rejected under 35 U.S.C. 102(e) as being anticipated by the Smith reference. The Applicants' invention as set forth in claim 6 is directed to an insert that is delineated by a fluid-permeable film. It is submitted that the Smith reference fails to teach or suggest an insert utilized with an absorbent element in a single-use hygienic or hygiene item.

With regard to Claim 7, it is submitted that the Smith reference fails to teach or suggest that the analysis means is positioned against one side of the separating means. The Examiner contends that the analysis device 34 disclosed in Smith has a visual display 36 when a side of the separating means 26 against which the device 34 is disposed is made transparent enough to allow a visual reading of the display unit 36. Reference is directed to column 5, line 65 through column 6, line 10. The Smith reference, at the cited location, is directed to the teaching that the article 10 can be provided with a pH sensitive component 34. The component 34 is fitted between the upper outer layer 26 and the lower outer layer 28. Smith specifies that the upper outer layer 26 can be selected from a material of specific density or composition to permit the color of the component 34 to be visualized by the wearer by reference to the upper outer layer 26 without having to disassemble the article to verify the

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color. In contrast, the separating means of the present invention is positioned in a location to separate bodily fluid in the analysis device from that in the absorbent element in an essentially fluid-tight manner. It is respectfully submitted that the use of such separating means in the visualizable upper outer layer of Smith would compromise the function of the article 10 as an absorbent item. Thus, it is submitted that the Smith reference fails to teach or suggest the Applicants' invention as set forth in claim 9.

Claims 11 and 12 also stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Smith reference. The Applicants' invention as set forth in claims 11 and 12 is directed to a hygiene item in which the separating means containing the analysis means is separable from the hygiene item. It is respectfully submitted that the Smith reference specifically teaches that the upper outer layer 26 of the article 10 is constructed so that the component 34 can be visualized by the wearer by reference to the upper outer layer 26 without having to disassemble the article to verify color. Thus, the reference teaches that any analysis means is not separable from the hygiene item. For this reason, it is submitted that the Applicants' invention as set forth in claims 11 and 12 is not taught, anticipated or rendered obvious by the cited reference.

With regard to claim 12, it is submitted that the Examiner has failed to demonstrate that the undergarment is an absorbent element that retains bodily fluid, and thus adhesives 36 detachably fastens the Smith article 10 to an undergarment substrate rather than an absorbent element.

Additionally, it should be noted that claims 6-14 depend either directly or indirectly from independent claim 1 to contain all of the limitations found therein. By this dependency, it is submitted that the applicants' invention as set forth in claims 6-14 is not taught, anticipated, or rendered obvious by the Smith reference for the reasons discussed previously in conjunction with claim 1.

Claim 15 also stands under 35 U.S.C. § 102(e) as being anticipated by the Smith reference. The Applicants' invention as set forth in claim 15 is directed to an analysis device comprising a visual display unit and means for measuring composition of bodily fluids directly introduced into the analysis device associated with the visual display unit. The device also includes means for maintaining the analysis device in separate fluid-tight contact with a

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single use hygiene item. The single-use hygiene item includes an absorbent element configured to absorb and retain bodily fluids other than those directly introduced into the analysis device. It is respectfully submitted that the Smith reference fails to teach or suggest a visual display unit having measuring means associated therewith for measuring the composition of bodily fluids directly introduced therein. The Smith reference further fails to teach or suggest an analysis device that can be maintained in separate fluid-tight contact with a suitable single-use hygiene item. For these reasons, it is submitted that the Applicants' invention as set forth in claim 15 is not taught, anticipated, or rendered obvious by the Smith reference.

Claims 4 and 5 currently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith et al. in further view of U.S. Patent No. 4,114,621 to Mims, Jr. The Examiner indicates that the Smith reference fails to describe an insert having sidewalls or edges that are folded around an upper side. The Examiner cites the Mims, Jr. reference as teaching an insert 11 designed to be placed in an absorbent element 10 similar to that of Smith et al.

The Mims reference is directed to an absorbent element 11 that comprises includes a chemically treated wick 40. The absorbent element 11 is insertable into a garment structure 10 such as an incontinence panty or the like. As shown in Figures 4 to 6, the absorbent element 11 comprises a fluid impervious backing. Within the fluid impervious backing there are provided a plurality of preferably four to six layers of filler 31 composed of highly absorbent material such as paper stock. The chemically treated wick 40 is provided directly adjacent or within the absorbent filler material such that absorbed liquid will come into contact with the wick 40. This draws material contained diffusely in the incontinence garment into contact with the wick 40. In contrast, the device of claims 4 and 5 is directed to an absorbent element isolated from the analysis device. It is submitted that isolation of the analysis device from absorbent material can advantageously affect analysis accuracy. This is not taught or suggested by the cited references. Additionally, it is respectfully submitted that the applicants' invention as set forth in claims 4-5 depends from independent claim 1 to contain all of the limitations found therein. By this dependency, it is submitted that the applicants' invention as set forth in claims 4-5 is not taught, anticipated, or rendered obvious by the cited references for the reasons discussed previously in conjunction with claim 1.

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Claim 10 currently stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith in view of Todd. The Examiner contends that the Smith reference teaches an upper layer of separating means 26 that permits the color of the display unit 36 to be visualized by the wearer. The reference fails to describe layer 26 as being transparent. The Examiner cites the Todd reference as disclosing an analysis device 10 having a display unit 24 providing a color change as an indication of analysis results. The display unit disclosed in Todd is considered to be immediately adjacent to a transparent outer layer of separating means 14. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the transparent layer as the upper side of the separating means of Smith et al. since Smith teaches an upper layer that allows visualization of the display unit through the separating means and Todd et al. describes a transparent material that would be suitable for such visualization. Claim 10 depends either directly or indirectly from claim 1 to contain all of the limitations found therein. By this dependency, it is submitted that the applicants' invention as set forth in claim 10 is not taught, anticipated, or rendered obvious by the cited references. For the reasons discussed previously in conjunction with claim 1.

Claim 15 also stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith in view of Todd. The Applicants' invention as set forth in claim 15 is directed to an analysis device that comprises a visual display unit and means for measuring the composition of bodily fluids directly introduced into the analysis device associated with the visual display unit. The analysis device also includes means for maintaining the analysis device in separate fluid-tight contact with a single use hygiene item that includes an absorbent element configured to absorb and retain bodily fluids distinct from bodily fluid directly introduced into the analysis device. The Applicant respectfully contends that the Smith reference lacks teaching of an analysis device used in conjunction with a single-use hygiene item. Furthermore, the Smith and Todd references lack any teaching that would suggest means for maintaining the analysis device in separate fluid-tight contact with a single-use hygiene item. Thus, it is submitted that the Applicants' invention as set forth in claim 15 is not taught, anticipated, or rendered obvious by the cited references.

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In summary, claims 1, 2, 5, 8, 9, 10, and 15 have been amended. Claim 3 has been canceled by this action. Additionally, arguments and discussion have been presented as to why the Applicants' invention as set forth in the claims is not taught, anticipated, or rendered obvious by the cited references. It is submitted that the Applicants' invention as set forth in these claims is in a condition suitable for allowance. Notice of Allowance is, therefore, respectfully requested.

Respectfully submitted,  
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Dated: August 25, 2004  
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